

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte RALUAN G. SOLTERO,  
KENNETH E. BURHOP, and  
JOHN F. HANSBROUGH

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Appeal No. 2001-1524  
Application No. 08/615,058

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ON BRIEF

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Before WINTERS, ADAMS and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the  
examiner's final rejection of claims 6-14, which are all the claims pending in the  
application.

Claims 6 and 11 are illustrative of the subject matter on appeal and are  
reproduced below:

6. A method for improving cardiac output, comprising administering  
chemically-modified, stroma-free hemoglobin to a patient suffering  
from burn shock in an amount effective to increase cardiac output.
11. A method for improving cardiac output, comprising administering  
diaspirin-crosslinked, stroma-free hemoglobin to a patient suffering  
from burn shock in an amount effective to increase cardiac output.

The references relied upon by the examiner are:

Tye	4,529,719	Jul. 16, 1985
Fischer et al. (Fischer)	5,428,007	Jun. 27, 1995
Kramer et al. (Kramer)	5,443,848	Aug. 22, 1995

Nguyen et al. (Nguyen), "Current Treatment of Severely Burned Patients," Annals of Surgery, Vol. 223, No. 1, pp. 14-25 (1996)

The references relied upon by appellants are:

Przybelski	5,334,706	Aug. 2, 1994
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Sharma et al. (Sharma), "Regional Circulatory and Systemic Hemodynamic Effects of Diaspirin Cross-linked Hemoglobin in the Rat," Art. Cells, Blood Subs., and Immob. Biotech., Vol. 22, No. 3, pp. 593-602 (1994)

#### GROUND OF REJECTION

Claims 6, 7 and 9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kramer in view of Fischer.

Claims 6-8 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kramer in view of Fischer, further in view of Nguyen.

Claims 11 and 12 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kramer in view of Fischer and Tye.

Claims 11-14 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kramer in view of Fischer and Tye, further in view of Nguyen.

We reverse.

#### DISCUSSION

According to the examiner (Answer, page 3), "Kramer teaches a method of overcoming circulatory shock due inter alia to burns characterized by increasing cardiac output...." The examiner finds (id.), "[a] 'particularly useful' embodiment of the method of Kramer is the inclusion of stroma-free hemoglobin,

which confers the useful property of increasing oxygen delivery to tissues.”

Kramer, however, does not teach chemically-modified stroma-free hemoglobin.

Answer, bridging paragraph, pages 3-4.

With regard to chemically-modified stroma-free hemoglobin, the examiner finds (Answer, page 4) that Fischer “teach[es] a method for treating human burn victims using hemoglobin that is recombinantly altered to have low oxygen affinity.” In this regard, the examiner finds (id.), “Fischer specifically teaches that his cross-linked hemoglobin advantageously increases tissue oxygenation in a patient.”

Based on this evidence, the examiner concludes (Answer, bridging paragraph, pages 4-5):

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of increasing cardiac output for burn shock victims disclosed by Kramer by using the modified, cross-linked hemoglobin taught by Fischer, because Kramer motivates a method comprising the use of hemoglobin to increase oxygen delivery to tissues, and Fischer teaches a modified hemoglobin particularly useful for carrying out this embodiment of Kramer’s [invention].

In response, appellants argue (Brief, page 8), “Kramer teaches increased cardiac output from the use of ‘limited ratios of hyperosmotic sodium acetate and sodium chloride.’” According to appellants (id.), Kramer “indicates that colloids within its disclosed compositions (which include for example, stroma-free hemoglobin ...) are added to the solution to increase blood flow and the oxygen carrying capacity of blood to improve oxygen delivery.” Therefore appellants conclude (id.), [t]he clear teaching from Kramer is that a hyperosmolar solution of sodium chloride and sodium acetate is necessary to increase cardiac output, not

chemically-modified, stroma-free hemoglobin as is required by appellants' claimed invention.

The examiner appears to agree with appellants' position, finding (Answer, page 8) that "Kramer increases cardiac output with a pharmaceutical composition comprising sodium chloride/acetate." However, the examiner argues (id.) that while increasing cardiac output by the addition of hemoglobin is not a goal of Kramer, the claims comprise the use of modified hemoglobin and therefore is open to encompass the use of additional elements. We cannot agree with the examiner's position.

While we agree that the use of the transitional term comprising opens the claim to include additional elements, appellants' claimed invention specifically requires that chemically-modified, stroma-free hemoglobin be administered in an amount effective to increase cardiac output. As both appellants and the examiner recognize, Kramer increases cardiac output with a pharmaceutical composition comprising 50:50 mixtures of sodium acetate:sodium chloride. See Kramer, column 5, lines 20-23. According to Kramer (column 5, lines 51-56), stroma-free hemoglobin serves to increase the oxygen carrying capacity of blood, not to enhance cardiac output. Therefore, in addition to the deficiency noted by the examiner, a second deficiency in Kramer is the failure to recognize the use of stroma-free hemoglobin to enhance cardiac output.

In this regard, appellants point out (Brief, pages 10-12), that neither Fischer, Nguyen, nor Tye describes increased cardiac output as a result of the administration of chemically modified stroma-free hemoglobin. We agree.

Accordingly, Fischer, Nguyen and Tye fail to make up for the deficiency in Kramer. In this regard, we remind the examiner as set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. ... Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.”

...

Most if not all inventions arise from a combination of old elements. ... Thus, every element of a claimed invention may often be found in the prior art. ... However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. ... Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [citations omitted]

In other words, “there still must be evidence that ‘a skilled artisan, . . . with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.’” Ecolchem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000). At best, the statement of the rejection establishes that individual parts of the claimed invention were known in the prior art, however, in our opinion, the prior art relied upon fails to suggest the desirability of making the specific combination as set forth in appellants’ claimed invention. As set forth in In re Spormann, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966)(“[t]hat

which may be inherent is not necessarily known.... Obviousness cannot be predicated on what is unknown”).

Accordingly, we reverse all of the prior art rejections of record.

REVERSED

Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Donald E. Adams	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
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Demetra J. Mills	)	
Administrative Patent Judge	)	

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